

The Doctor's Chart

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HIPAA: Administrative Simplification Standard for Electronic Transactions

As many of you may be aware, the last issue of *The Doctor's Chart* contained a brief look at the health information privacy regulations recently promulgated pursuant to the mandate of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Continuing our focus on this complex piece of federal law, I would like to shift now to another aspect of HIPAA: the emphasis on encouraging administrative simplification of health care records and payment through the use of electronic medical records and billing systems.

In enacting HIPAA, Congress took special note of the administrative streamlining that would accrue from the implementation of a comprehensive electronic data set. Congress accordingly granted authority to the Secretary of Health

and Human Services to adopt standard data sets and identifiers, and to require health plans to accept data meeting these new standards. On August 17, 2000, HCFA, now The Center for Medicare and Medicaid Services ("CMS"), published the transactions and codes sets final rule ("Final Rule"). This mandate establishes national standards for eight particular electronic transactions and for the code sets that are



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to be used therewith. The regulations became effective on October 16, 2000 and covered entities are required to be in compliance with the new standards by October 16, 2002. Small health plans, defined as health plans with annual receipts of \$5 million or less, however, have until October 16, 2003 to comply.

The Final Rule applies to the following "covered entities": (1) health plans; (2) health care clearinghouses; and (3) health care providers that maintain or transmit health information in electronic form. A "health plan" is defined as an individual or group plan that provides, or pays the cost of, medical care. A "health care clearinghouse" is defined as an entity that processes or facilitates the processing of non-

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standard data elements of health information into standard data elements. Finally, the rule provides a very broad definition of “health care provider,” a person or organization who furnishes, bills, or is paid for health care services in the normal course of business. “Health information” is oral or recorded information, in any form, that relates to (1) the health or condition of an individual; or (2) the provision of healthcare; or (3) the payment for the provision of healthcare; and is created or received by a provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearinghouse.

“Business associates,” individuals or organizations who perform a function or activity on behalf of a covered entity, are similarly covered by the broad scope of the regulations. Thus, the Final Rule encompasses both transactions conducted between covered entities via electronic media and transactions conducted by a covered entity via a business associate. As noted in the last issue of *The Doctor’s Chart*, this broad definition of “business associate” is problematic in that it brings under the rule’s purview parties which heretofore have not had to comply with such an intricate set of standards. Employer administered group health plans with fewer than 50 participants, however, are not covered by these standards. Moreover, health care providers electing to use direct data entry with a health plan are similarly left outside the scope of the Final Rule. It should be pointed out both that the rule provides no exception for transactions between affiliated entities and that the rule does not prohibit health care providers from submitting claims on paper. In the latter situation, however, a health plan can require the same data for paper transactions as it does for electronic transactions.

The regulations define a “transaction” as the transmission of information between two parties to carry out financial or administrative activities related to health care. The Final Rule imposes standardized formats, code sets and data content for the following eight transactions:

- Coordination of benefits transactions;
- Health care payment and remittance advice transactions;
- Health care claims and equivalent encounter information transactions;
- Health care claim status transactions;
- Enrollment and disenrollment in health plan transactions;
- Eligibility for health plan transactions;
- Health plan premium transactions; and
- Referral certification and authorization transactions.

The rule mandates that health plans, by the aforementioned compliance dates, have the capacity to accept and send standard transactions that they currently conducts, but does not support electronically. This means, for instance, that if a health plan today certifies its referrals entirely on paper, that plan is required to have the capacity to perform that same function electronically by the applicable date. Moreover, health plans are proscribed from refusing standard transactions. It is important for providers to note, however, that a standard transaction alone does not create a relationship or liability.

The Final Rule requires covered entities to employ certain prescribed code sets to encode data elements when conducting one of the transactions listed above in an electronic format with another covered entity. The Final Rule has adopted the following code sets:

- The *International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM), Volumes 1 and 2* for diseases, injuries, impairments, etc.;
- The *International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM), Volume 3* for prevention, diagnosis, treatment and management;
- The *National Drug Codes* for drugs and biologicals;
- The *Code on Dental Procedures and Nomenclature* for dental services;
- A combination of the *Health Care Financing Administration Common Procedure Coding System (HCPCS)* and the *Current Procedural Terminology, Fourth Edition (CPT-4)* for physician services and

other health care services; and

- The *HCPCS* for all other substances, equipment, supplies, including medical supplies, orthodontic and prosthetic devices, and durable medical equipment.

Sanctions, in the form of civil monetary penalties, for failure to comply with the new standards, provide what CMS considers to be requisite “stick” to enhance the likelihood of compliance. CMS is henceforth authorized to impose penalties of not more than \$100 per violation, not to exceed \$25,000 in each calendar year for a single violation, on anyone who falls below the new information threshold. As with other federal schemes, the administrative simplification standards entail more severe penalties for knowing, willful and deliberate acts. Any person who “knowingly misuses a unique health identifier, or obtains or discloses individually identifiable health information” is subject to a fine of not more than \$50,000 and imprisonment of not more than one year. For violations conducted “under false pretenses” the fine may not be more than \$100,000, along with a term of imprisonment of not more than five years. Finally, for violations conducted with an intent to use the individually identifiable health information for commercial or personal gain, the penalties are stricter still, with a fine of up to \$250,000 and a prison term of not more than ten years.

There are about 400 formats for electronic health claims employed today in the United States. It is abundantly clear that this lack of standardization hinders the ability of providers and health plans to achieve the financial and administrative benefits that are brought through efficiency. The implementation of a standard format for electronic transactions, and for the code sets used therein, will improve both federal and private health programs, as well as the overall efficiency and effectiveness of the health care industry. Indeed, the use of a standard format for the electronic transfer of information is anticipated to accrue \$30 billion in savings over the next decade. CMS, which has estimated that the cost of compliance to health care providers will run to \$3.6 billion, has indicated that those providers will ultimately save \$16.7 billion over the same period of time. Some observers, however, have noted that the nature and complexity of these standards, coupled with the equally intricate privacy regulations, along with the other regulations that will eventually be enacted pursuant to HIPAA’s mandate, such as the security regulations, will ultimately lead to compliance costs greater than those entailed by Y2K. Thus, covered entities will do well to begin the compliance process at the earliest possible date. Although HIPAA’s requirements will not be enforced in the immediate future, a great proportion of providers remain unaware of the onerous duties that the compliance process will entail. Given the intricacy of these new standards, moreover, covered entities would be well served to seek legal assistance in determining exactly what needs to be done to become HIPAA compliant.

HHS Offers First Guidance on HIPAA Privacy Protections

The Office for Civil Rights in the Department of Health and Human Services on July 6 released its first guidance regarding what health plans and providers must do to comply with HIPAA’s privacy protections. The guidance, offered in a question and answer format, provides much needed, and indeed anticipated, clarification of certain key provisions of the privacy rule. The privacy regulation, which was published on December 28, 2000, and which took effect on April 14 of this year, requires covered entities to comply by April 14, 2003. Small health plans have an additional year to comply. As discussed in greater detail in the last issue of *The Doctor’s Chart*, the crux of the privacy rule is the establishment of national standards to protect individuals’ medical records and other protected health information (“PHI”).

In issuing the guidance, DHHS Secretary Tommy Thompson noted, “This guidance is an opening step in helping physicians, health care providers, and health plans understand their obligations to patients under the rule.” DHHS expressed its wish that the guidance will alleviate confusion about the rules, while further recognizing the necessity of taking steps to address problems that the rule seems to have created. “Hospitals do not have to build private, soundproof rooms to prevent overheard conversations about a patient’s condition, as some mistakenly believed,” DHHS remarked. Instead, the rule merely requires “reasonable safeguards” to be implemented. The guidance offers assistance on exactly what constitutes “reasonable safeguards” for a num-

ber of the rule’s requirements, including its standards for consent, minimum necessary disclosures of PHI, oral communications, and business associates. What follows is a brief overview of some of the highlights contained in the guidance.

CONSENT

Generally speaking, the privacy rule has created a federal mandate that most doctors, hospitals, and other health care providers obtain a patient’s written consent before using or disclosing the patient’s PHI to carry out treatment, payment, or health care operations (“TPO”). The guidance offers a number of elaborations on this general rule:

- Pharmacists may give advice regarding over-the-counter medications without obtaining an individual’s consent, provided that the pharmacist does not keep a record of the communication.
- Patient consent may be disclosed in electronic form.
- A patient’s signed consent for use and disclosure of PHI is valid until it is revoked.
- Friends and family may pick up prescriptions for patients. Patients, moreover, are not required to provide the names of these individuals to their pharmacist in advance.
- Organizations may continue to use PHI obtained under a patient consent or authorization obtained before the applicable compliance date for treatment, payment, or healthcare operations, even if the previous consent was limited to disclosure for payment.
- OCR also expressed its awareness of certain unintended problems that have resulted from the privacy rule. The guidance noted, for instance, that the privacy rule as written does not permit (1) pharmacists to use PHI to fill prescriptions telephoned in by a patient’s physician if the patient is new to the pharmacy and has not yet provided written consent thereto, or (2) direct treatment providers, such as specialists or hospitals, to whom a patient is referred for the first time, to use PHI to set up appointments or schedule surgery or other procedures before obtaining the patient’s written consent. OCR made it clear that it is cognizant of these unintended consequences, and that it will be proposing changes in the near future to address these problems.

MINIMUM NECESSARY

The privacy rule generally requires covered entities to take reasonable steps to limit the use or disclosure of, and requests for, PHI, to the minimum necessary to accomplish the intended purpose. There are, however, a number of instances to which the minimum necessary standard does not apply. Recognizing the difficulty involved in deciding exactly what constitutes the minimum necessary amount of PHI, the guidance offers a number of tips:

- Under the minimum necessary standard “covered entities need not limit information uses and disclosures to those that are absolutely needed to serve the purpose [at issue]. Rather, [the] reasonableness standard . . . calls for an approach consistent with the best practices and guidelines already used by many providers today to limit the unnecessary sharing of medical information.”
- Expressing awareness of the fact that it is frequently necessary for the entire medical record to be used, the guidance notes, “The rule recognizes that the covered entity is in the best position to know and determine who in the workforce needs access to [PHI] to perform their jobs. Therefore, the covered entity can develop role-based access policies that allow its health care providers and other employees, as appropriate, access to patient information, including the entire medical records, for

treatment purposes.”

- Although, as indicated above, the regulations do not require covered entities to redesign their facilities, certain, less extensive safeguards are required. The guidance pointed out, for instance, that “covered entities may need to make certain adjustments to their facilities to minimize access to [PHI], such as isolating and locking file cabinets or records rooms, or providing additional security, such as passwords, on computers maintaining personal information.” Covered entities would be wise, moreover, to consider whether they have the ability to reconfigure their record systems so as to allow access to only certain fields.
- There is no prohibition against covered entities maintaining patient medical charts at bedside, or requiring them to shred empty prescription vials or isolate X-ray boards. Noting that this particular aspect of privacy has posed profound concerns throughout the healthcare community, OCR indicated that further guidance would be forthcoming on this point.
- Finally, in another example of the law of unintended consequences, OCR pointed out that the privacy rule can be read to prohibit the use of sign-in sheets in physician waiting rooms. The agency accordingly expressed that it would be issuing modifications to the rule so as to make clear that this practice is permissible.

ORAL COMMUNICATIONS

Recognizing the clear necessity for including oral communications under the privacy rule, the regulations require covered entities to reasonably safeguard PHI, including oral information, from any intentional or unintentional use or disclosure that is in violation of the rule. Covered entities are required to have in place appropriate administrative, technical, and physical safeguards to protect the privacy of all PHI. The guidance is helpful in this particular vein in that it dispels, to some extent, the commonly held perception that providers must eliminate any and all risks of disclosure.

- In setting forth the position that DHHS does not expect the vitiation of all risks, the guidance noted the standard that it would apply: “In determining whether a covered entity has provided reasonable safeguards, [OCR] will take into account all the circumstances, including the potential effects on patient care and the financial and administrative burden of any safeguards.” The guidance further noted safeguards that would be considered reasonable, including speaking quietly when discussing a patient’s condition and avoiding patients’ names in public hallways.
- The guidance also made clear that HIPAA’s privacy rule is not meant to forbid providers from talking to each other and to their patients. Moreover, OCR made clear that it regards overhead communications, such as, in a busy emergency room, providers speaking loudly, so as to ensure appropriate treatment, as unavoidable. Finally, the guidance indicated that the following practices would be permissible: (1) health care staff may orally coordinate services at hospital nursing stations; (2) nurses or other health care professionals may discuss patients’ conditions over the phone with a patient, provider, or family member; (3) health care professionals may discuss lab test results with patients and/or other providers in a joint treatment area; and (4) health care professionals may discuss patients’ conditions during training rounds in an academic or training institution.
- There is no requirement that providers must give patients access to the provider’s oral communications.

BUSINESS ASSOCIATES

One of the most perplexing aspects of the privacy rule is the provision relating to business associates of covered entities. A business associate is a person or entity who provides certain functions, activities, or services for or to a covered entity, involving the use and/or disclosure of PHI. Given the fact that in today’s health care environment most providers and plans, rather than carrying out all of their activities on their own, make ample use of business associates in providing care, this provision is especially important. Generally

speaking, HIPAA requires covered entities that provide PHI to business associates to obtain, usually by contract, satisfactory assurances that the business associate will use the information only for the purposes for which they were engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with its duties to provide individuals with access to health information about them. The rule clearly indicates that PHI may be disclosed to a business associate for the sole purpose of helping covered entities carry out their health care functions. Equally clear, moreover, is HIPAA's insistence that PHI may not be disclosed for the business associate's independent use.

- In an effort to assuage widespread fear that covered entities may be liable for the privacy violations of a business associate, the guidance unambiguously states that that is not the case. Indeed, the guidance goes further, noting that covered entities are not obligated to actively monitor or oversee the means by which their business associates carry out safeguards or the extent to which the business associate adheres to the requirements of the contract. Furthermore, OCR makes plain that a business associate's violation of the terms of the contract does not, in and of itself, constitute a violation by the covered entity.
- In an effort to forge a reasonable compromise position as to the responsibilities of a covered entity vis-à-vis a business associate, the guidance offers the following point: "If the covered entity becomes aware of a pattern or practice of the business associate that constitutes a material breach or violation of the business associate's obligations under the contract, the covered entity must take 'reasonable steps' to cure the breach or to end the violation." Frustratingly, however, the guidance defines "reasonable steps" to "vary with the circumstances and nature of the business relationship."

Beyond the aforementioned areas, OCR offers additional guidance for the following aspects of the privacy rule: (1) parents and minors; (2) health-related communications and marketing; (3) research; (4) restrictions on government access to health information; and (5) payment. As described elsewhere in this document, with compliance dates fast approaching it is critical for covered entities of all sizes to begin the compliance process. If you have already started down this obstacle-ridden path, you are ahead of the game. If not, you would do well to start thinking about compliance as soon as possible. HIPAA's broad scope, complex structure, and daunting penalties provide reason enough to start moving on this matter. If you have questions or concerns, please contact your healthcare attorney.

Wisconsin Cases of Note

Supreme Court—It's Not the Alleged Misdiagnosis, But Rather The Injury That Results Therefrom, that Triggers Running of Limitations Period

Media attention on medical malpractice has never been as acute as it is today. With politicians in Washington chomping at the bit to effect some sort of tort reform, this trend shows no signs of abatement. Although egregious

incidents of the sort discussed herein are rare, the Wisconsin Supreme Court's ruling in the following case provides guidance to both potential plaintiffs and defendants. Jennifer Paul first complained of headaches to her local clinic, the Skemp Clinic ("Skemp"), in 1984. During the next ten years, she made similar complaints to the clinic, as well as claims of nausea, vomiting, and dizzy spells. In December 1994, Skemp diagnosed Jennifer as having sinus-related headaches. On May 22, 1995,

emergency room workers determined that Jennifer had suffered from an arteriovenous malformation ("AVM") in the right cerebellum that had ruptured and caused excessive hemorrhaging. Jennifer died the next day as a result of this injury.

Jennifer's parents ("plaintiffs") filed suit in state court against Skemp and several of its doctors on March 16, 1998 ("defendants"), alleging medical

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Court of Appeals: Capping Non-Economic Damages in Med Mal Cases is Constitutional

malpractice. Defendants moved for summary judgment, alleging the statute of limitations period barred plaintiffs' claim. The trial court ruled in defendants' favor, determining that the limitations period began running at the time of the last alleged misdiagnosis, and accordingly that plaintiffs were barred from seeking any relief on this theory. Plaintiffs appealed.

Reversing the trial court's grant of summary judgment, the Wisconsin Supreme Court held that the action was filed within the limitations period under Wis. Stat. § 893.55(1)(a) because the event that triggered the running of the limitations period was not the alleged misdiagnosis, but rather the injury that resulted therefrom, the rupture of the AVM in Jennifer's brain. Relying on reasoning set forth by the Virginia Supreme Court in *St. George v. Pariser*, 484 S.E.2d 888 (Va. 1997), Wisconsin's high court concluded that "[a] misdiagnosis, in and of itself, is not, and cannot, be an actionable injury" and that "[t]he misdiagnosis is the negligent omission, not the injury."

In an opinion handed down December 19, the Wisconsin Court of Appeals reversed a lower court's ruling, holding that the state legislature can constitutionally limit the amount of non-economic damages that a person injured by a healthcare provider can recover. Wisconsin law establishes a cap on the recovery of non-economic damages in healthcare provider malpractice cases, limiting such damages to \$350,000 for each occurrence.

The case in question arose from a lawsuit filed by Audrey Guzman against several healthcare providers for negligent treatment. Guzman suffered spinal cord injuries and became a quadriplegic after receiving treatment in June 1997 for a cervical spine fracture at St. Francis Hospital. Guzman sued St. Francis, as well as the other providers who had participated in her care. The Circuit Court for Milwaukee County held that the legislature cannot constitutionally limit the amount of damages that a person injured by their healthcare provider can recover because doing so violates the right to trial by jury and the separation of powers between the legislative and judicial branches of government.

The Court of Appeals reversed the trial court's ruling, holding that the legislatively imposed limit was constitutional. The court noted that the legislature has determined that "[t]aming the costs of medical malpractice" by limiting the right of patients injured by medical malpractice to recover for their injuries 'ensur[es] access to affordable health care' for all, and that this is a 'legitimate legislative objective.'" Moreover, the court pointed out, the legislature's cap does not infringe on a plaintiff's right to a jury trial, because plaintiffs can still have the issue of healthcare provider liability decided by a jury, which will also assess damages. Likewise, the appellate court found that the cap did not violate the separation of powers doctrine.



CHIROPRACTIC NEWS

Ohio Chiropractor Receives Eight Months Internment, Fine for Involvement in Kickback Scheme

A federal judge recently sentenced a Cleveland, Ohio **chiropractor** to four months in prison and four months of home detention and ordered him to pay assessments in the amount of almost \$67,000. Chiropractor John D. Strom pleaded guilty in October 2000 to four counts of conspiring to defraud patients of their intangible right of honest services and one count of mail fraud.

The case against Strom, brought by the U.S. Attorney's Office for



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the Northern District of Ohio, began with an FBI inquiry into Strom's business activities. The FBI's investigation determined that Strom, between October 1991 and April 1998, had conspired with four mobile medical testing companies, receiving kickbacks for referring patients and ordering tests. The FBI found that certain business arrangements, ostensibly lease contracts, entered into between Strom and the mobile testing companies, Diagnostic Testing of Ohio, Cardiac Interpretations Inc., Medical Dynamics Inc., and Ultrasound Diagnostic Service Inc., were actually agreements to exchange kickbacks for medical testing referrals. Between January 1992 and April 1998 Strom received, and caused to be received, kickback checks, through the U.S. mail, totaling nearly \$63,000.

The conspiracy evidently extended to co-owner and employee chiropractors of Strom's seven clinics. The U.S. attorney's office noted that Strom not only actively encouraged his co-workers to order tests from the aforementioned medical testing companies, but also pushed them to negotiate their own ostensible "lease arrangements." Strom allowed his co-workers to do whatever they liked with any money they received as kickbacks from the four mobile testing companies. This policy had the added financial advantage of sparing Strom the necessity of providing salary increases.

Strom could have received a maximum statutory penalty of five years imprisonment, as well as a fine of \$250,000 on each charge.

Five Charged in \$10 Million Chiropractic Scam

Federal prosecutors recently announced that a New York **chiropractor** and four others have been charged with 115 counts of conspiracy, health care fraud, and mail fraud. In a swindle that generated more than \$10 million in false Medicare, no-fault automobile insurance, workers' compensation, and private insurance billings, the defendants allegedly operated a system whereby chiropractic services were disguised as rehabilitative medical services. The defendants have surrendered voluntarily to face these charges.

Andrew Orlander, the chiropractor who prosecutors allege to be the ringleader of this scam, has also been charged with money laundering for the manner in which he handled the proceeds from this operation. Orlander is accused of controlling and operating Allstate Managed Services Organization, LLC, also named as a defendant, as a means to cover up the false billings. Through Allstate, prosecutors allege, Orlander converted chiropractic practices into medical practices, while employing a series of complex contractual arrangements to maintain control over those entities.

In a maneuver undertaken to comply with New York law, Orlander hired and paid physicians to serve as owners of the medical professional corporation that he controlled. This corporation presided over a network of facilities in Westchester and Rockland counties in the northern suburbs of New York City. All of the profits realized from those facilities were funneled through separate management companies allegedly set up by Orlander. The point of all of this was to allow Orlander to bill for more services, and at higher rates, than if his rehabilitative facilities had remained chiropractic in nature.

Prosecutors allege that the facilities billed for services that were never rendered, including diagnostic tests and 15-minute physical therapy sessions that actually ran much shorter, and for physical therapy services provided by unlicensed personnel. Prosecutors also charge that the facilities misrepresented the nature of the billed services and their medical necessity.

Recent Decision Evidences OIG's Continued Focus on Fraud & Abuse

Federal Judge Scott O. Wright recently sentenced a Missouri-based **clinical psychologist** to five years probation for filing fraudulent Medicare reimbursement claims. The psychologist, Karen R. Casada, pleaded

guilty in federal court to one count of health care fraud and one count of mail fraud on November 23, 2000.

Casada was indicted on August 31, 2000 by a federal grand jury for allegedly defrauding Medicare by submitting upcoded reimbursement requests. Upcoding, a term which refers to coding a claim requesting payment for a service reimbursed at a rate higher than the service provided, has been a lightning rod for OIG involvement in the past, a trend which shows no sign of abatement.

The indictment indicated that Casada submitted 3,072 Medicare claims on behalf of 102 patients between 1996 and 1998, for which she received almost \$443,000. The OIG's investigation demonstrated that \$92,000 of that total was obtained as a result of upcoding.

Casada, who is required to spend the first 10 months of her probation in home detention, has already paid full restitution.

AT LEAST YOUR WIFE OR HUSBAND DOES NOT HAVE TO TESTIFY AGAINST YOU (if they don't want to)

The U.S. District Court for the Northern District of Illinois recently held that the spousal testimonial privilege could be asserted in a civil action for injunctive relief that paralleled a criminal proceeding. The privilege could be asserted, the court ruled, because otherwise the government would have the opportunity to use, in the criminal proceeding, any adverse testimony that might be elicited in the civil case.

The issue was raised when the government sought an injunction to maintain a freeze on the assets of Krishnaswami Siram, the erstwhile owner of an in-home medical services company who has been indicted for mail fraud and health care fraud. The government, based on its claim that Siram submitted false claims for Medicare reimbursement, sought forfeiture of assets in the amount of more than \$3 million. In pursuit of its claim, government attorneys announced that they would call Siram's wife to answer questions regarding her involvement in his medical business.

Siram's wife sought to invoke the spousal testimonial privilege, which allows the testifying spouse to assert a privilege against providing harmful testimony against the other spouse. In response, the government argued that none of the testimony that it sought to elicit would be harmful to Siram.

Notwithstanding a prevalent judicial trend to restrict its use, the court held that Siram's wife could invoke the privilege under these circumstances. Noting that application of the evidentiary privilege would continue to be determined on a case-by-case basis, the court pointed out that the government had failed to provide immunity or assurance that it would not use the testimony in the criminal case.

If Called Before Grand Jury, Err on the Side of Caution

The recent conviction of a Pennsylvania physician for Medicare fraud should serve as a warning to all health care professionals: if you are called before a grand jury to testify in an investigation of your employer's Medicare billing practices, call your lawyer. This warning comes at the expense of Anselmo Gomez, a physician recently convicted of Medicare fraud on the basis of testimony he gave before a grand jury investigation into the billing practices of his employer.

The case arose through a Medicare fraud investigation into Gomez's erstwhile employer, Three Rivers Physical Therapy and Occupational Therapy Center. Gomez cooperated voluntarily with the investigation and was later subpoenaed to appear before a grand jury. He appeared without counsel and, in the course of his testimony, made self-incriminating statements. Gomez was subsequently convicted of sixteen counts of health-care fraud arising from Medicare billing, for which he was sentenced to concurrent twenty-four month terms of imprisonment on each count, followed by three years of supervised release.

Gomez filed an appeal before the U.S. Court of Appeals for the Third Circuit, contending on the basis of the Fifth Amendment that prosecutors should have told him he had a right not to testify against himself.

The court rejected Gomez' argument, holding that although Gomez was compelled to appear before the grand jury, he was not compelled to testify, and that the Fifth Amendment does not require that a citizen subpoenaed to appear before a grand jury be informed of the right against self-incrimination. The court noted, moreover, that because nothing unfair took place before the grand jury, such as questioning that addressed issues beyond those Gomez could have reasonably expected, and because Gomez had adequate opportunity to consult with counsel, there was no reason to impose Fifth Amendment warnings for grand jury witnesses.

Republication of Report Extends Statute of Limitation, Allows Physician to Bring Otherwise Barred Defamation Suit

The Texas Court of Appeals recently held that because a physician can suffer a new injury every time an allegedly defamatory report is published, republication can keep a claim alive for statute of limitations purposes, even if the initial publication occurred outside the limitations period.

The case in question focused on a report Methodist Hospital filed with the National Practitioner Data Bank about one of its physicians, Dr. James M. Wheeler. Wheeler, who had privileges to practice at Methodist from 1988 until 1995, resigned from the hospital in March 1995 following an internal dispute. Upon receiving Wheeler's resignation, Methodist informed him that because he had voluntarily resigned while under investigation, the hospital would, as required by law, report the incident to the National Practitioner Data Bank through the Texas State Board of Medical Examiners.

Wheeler, according to the report Methodist submitted, was "summarily suspended for failure to adhere to the terms of a practice improvement plan." Wheeler, arguing that this statement was false, sued Methodist in 1996 for defamation and business disparagement.

The appellate court held that although Wheeler's defamation claim failed to meet the one year statute of limitations, Methodist's republication of the report twice within a year of Wheeler's filing his suit acted to extend the statute, thereby allowing Wheeler's defamation claim to proceed. Whether Wisconsin or Michigan courts would reach a similar conclusion is an issue that has not yet come to fore. Still, providers should note that the logic behind the argument advanced in the Texas case would seem to be applicable in both states. There is a two-year statute of limitations for defamation in both Wisconsin and Michigan.

Michigan Federal Court: No Right to Physician-Assisted Suicide Protected by Ninth and Fourteenth Amendments

In the most recent judicial opinion on the ever-contentious issue of physician-assisted suicide, the U.S. District Court for the Eastern District of Michigan has held that there is no Ninth or Fourteenth Amendment protection for doctors to engage in that activity. The court's decision in *Cooley v. Granholm* is consistent with the U.S. Supreme Court's point of view on this subject.

The case originated with two Michigan physicians, Roy Cooley and M.W. El-Nachef (“plaintiffs”), who are regularly consulted by patients who suffer from incurable medical conditions. These consultations, plaintiffs contend, occasionally involve requests made by patients for assistance in ending their own lives. Plaintiffs, however, have always had to demur from such requests, even when, in their best medical judgment, such assistance would be warranted, for fear of criminal prosecution and disciplinary action were they to act in accordance with their patients’ requests.

Dissatisfied with their untenable position, plaintiffs brought suit against the Michigan attorney general and the chair of the Michigan Board of Medicine (“defendants”), arguing in federal court that Michigan law “imposes an undue burden on the right of such patients to be free of such unbearable and irremediable suffering, and that Michigan law unreasonably interferes with the right of doctors to practice medicine according to their best professional judgment.” Plaintiffs sought a declaratory judgment that competent adults have a right, protected by the Ninth and Fourteenth Amendments, to choose to be free of such suffering, including “the right to have appropriate medical assistance in voluntarily terminating that unbearable and irremediable suffering and what little remains of their life.”

The court granted defendant’s motion for summary judgment and dismissed plaintiffs’ case. In rejecting plaintiffs’ contention that the Due Process Clause of the Fourteenth Amendment entails a right to physician-assisted suicide, the court noted that the U.S. Supreme Court has previously held that “the asserted ‘right’ to assistance in committing suicide is not a fundamental liberty interest” and that “the history of the law’s treatment of assisted suicide in this country has been and continues to be one of rejection of nearly all efforts to permit it.” The Michigan court declined to deviate from the Supreme Court’s analysis of this issue as set forth in *Washington v. Glucksberg*, noting that even if plaintiffs’ claim somehow fell outside of *Glucksberg’s* sweep, the court “is not convinced that it should break new ground and expand the scope of substantive due process to include the right to physician assisted suicide under the circumstances presented here.” The court, moreover, found plaintiffs’ argument that they had a Ninth Amendment right to assist in patients’ suicide to be equally devoid of merit, pointing out that the U.S. Supreme Court has never before used the Ninth Amendment “as an independent source of rights protected from governmental interference.”

Although the court explicitly recognized the highly emotional nature of the debate surrounding physician-assisted suicide, its holding clearly rejected the notion that courts are the appropriate forum for settling this issue. Rather, the court pointed out, this “question clearly is a policy one that is appropriately left to the citizenry for resolution.”

Valuable Information For Individuals, Small Group Physician Practices in OIG Compliance

The OIG’s final guidance on voluntary compliance plans for individual and small group practices, *Compliance Program Guidance for Individual and Small Group Physician Practices*, a document released September 25, 2000, provides valuable information and infuses a refreshing degree of flexibility into the compliance process. The document is designed to help small physician groups develop a plan to “identify both erroneous and fraudulent claims and help ensure that submitted claims are true and accurate.”

The draft compliance plan, issued in the June 12 *Federal Register*, was met with severe criticism from the health care and legal communities. Many groups excoriated the guidance, contending that it was too restrictive and would prove to be too costly for small practices to implement. In response to comments by physicians concerned with the burden of implementing compliance measures in conformity with the

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draft, the OIG has softened its overall approach by emphasizing the voluntary nature and flexibility of the guidance. OIG attorney Kimberly Brandt, one of the authors of the draft and final Guidances, noted, “it is important for the physician community to understand that the Guidance is not mandatory in nature but can be used as an excellent compliance resource tool for physicians implementing compliance within their practices.”

In announcing the Guidance, then-Inspector General June Gibbs Brown commented, “We are encouraging physician practices to adopt the application of compliance principles in their practice, rather than implement rigid, costly, formal procedures.”

While many observers, particularly physicians, have applauded the OIG’s effort, noting their satisfaction with the enhanced flexibility of the document, others have expressed concerns that doctors will mistakenly interpret this flexibility as a reason to push compliance issues to the side. Accordingly, it is important for physicians to understand that, despite this increased elasticity, the risks that they face and the applicable laws have not changed. Physicians are encouraged to review the final Guidance and to begin to address their risk areas. Moreover, physicians should remember that federal, state and insurance agencies continue to strictly review these “voluntary” guidelines in searching out potential instances of fraud. If an audit occurs, investigators will undoubtedly consider the extent to which a practice meets the agency’s expectations.

Unlike the compliance program guidance designed for other health care providers, the OIG’s approach in the final document takes cognizance of the fact that doctors may not have the ability to implement each and every element entailed in a standard compliance program. Rather than recommending that practices implement an “effective” compliance program with formal procedures, the final Guidance accordingly advocates “the active application of compliance principles.” Thus, the final Guidance differs from the proposed version in that it does not suggest that physician practices implement all of the seven standard components on which compliance programs are based. Moreover, the agency has abandoned its earlier recommendation for a formal code of conduct, recognizing the impracticality of such for small group practices. Generally speaking, then, the larger a practice and the more resources it has, the more it ought to do. Smaller practices, on the other hand, should take advantage of the OIG’s newfound flexibility by putting into place several of the suggested steps, focusing on coding and billing, medical necessity, documentation, and improper inducements.

The final guidance reworks the seven compliance program elements set forth in the draft Guidance into a “suggested order of the steps a practice should take to begin the development of a compliance program.” The seven suggested steps include: (1) conducting internal monitoring and auditing through performance of periodic audits; (2) implementing compliance and practice standards by developing written standards and procedures; (3) designating a compliance officer to monitor efforts and enforce practice standards; (4) conducting appropriate training and education on practice standards and procedures; (5) responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate government entities; (6) developing open lines of communication; and (7) enforcing disciplinary standards through well-publicized guidelines.

Although a complete analysis of the OIG’s guidance is not possible here, the following is a brief summary of the aforementioned steps:

Step One—Audit and Monitor

At the outset, a baseline audit must be conducted, the goal of which is to identify areas of risk. The OIG suggests that practices should, on at least an annual basis, randomly pull patient records for detailed billing and coding review. At least five records per payor and five to ten records per physician should be reviewed. The agency further recommends documenting the individual who conducts the audit, the date on which it occurred, along with any problems discovered and the actions taken in response thereto. In the Guidance, the OIG delineates four potential risk areas affecting physician practices: (1) coding and billing; (2) reasonable and necessary services; (3) documentation; and (4) improper inducements, kickbacks and self-

referrals.

While the OIG is insistent on the importance of this initial audit, the agency fails to recognize in writing several of its less favorable aspects. The OIG, for example, does not offer comment on the inherent risks a practice assumes in undertaking auditing activities. The agency fails to mention that unprivileged audits can serve to document a practice's problems. This potential danger is only enhanced by the fact that such audits must be provided to the government upon request. Consequently, physician practices undertaking auditing activities as part of their compliance programs will be well served to seek legal counsel for assistance.

Step Two—Develop Practice Standards and Procedures

The OIG recommends as its second step the development of practice standards and procedures to address the problems identified as risk areas. To this end, the agency suggests including in the practice's personnel handbook and job descriptions a statement to the effect that employees are required to comply with all practice procedures, as well as with state and federal regulations. Employees should be asked to sign and date a statement acknowledging their familiarity with this policy.

The agency is clear in its contention that physician practices should set forth in great detail the procedures to be followed in every staff task. However, many smaller practices will find that they lack the resources to comply with this suggestion. Accordingly, smaller practices might want to consider attaching a line to clinical job descriptions regarding the pertinent treatment guidelines that are to be used. Size notwithstanding, all practices should consider having their senior employees supervise the progress of each new hire. Finally, the agency notes that practices should compile a binder for HCFA directives, carrier bulletins, coding updates, HHS alerts and advisory opinions, and OIG inspection notices and audit reports.

Step Three—Designate a Compliance Officer

After the audits have been conducted and risks identified, one member of the practice should endeavor to develop a corrective action plan. In an effort to be flexible, the OIG notes that this officer may take full responsibility for all compliance activities or play a more limited role in resolving whatever issue has compelled the corrective action. Accordingly, the agency has now recognized the availability of several options, including allowing practices to designate compliance contacts in lieu of a designated compliance officer, outsourcing for an officer, and even sharing compliance officers with other practices. Small and solo practices should take note; you will typically find it most cost-effective to distribute different duties among several compliance contact staffers.

Physician practices considering collaborative compliance officers, however, should remain cognizant of potential anti-kickback implications. Furthermore, practices that decide to share or outsource this duty will want to assign practice liaison authority to a fairly high-level staff member. If a practice chooses to delegate full compliance authority to a single individual, it is crucial that the practice bestow upon the person selected the corresponding authority to report problems and implement the necessary response.

Step Four—Conduct Training and Education

Ever cognizant of the incredibly complex nature of America's health care system, the OIG contends that efforts at raising awareness are the next logical step after problems have been identified and an individual has been selected to oversee compliance training. Practice-wide compliance training should start by drafting a memo that highlights potential problem areas, such as noticeable changes in the number and type of claims rejections or reductions, as well as payor challenges to medical necessity or the validity of particular claims. This memo should be distributed throughout the practice and posted in common areas.

Each practice will want to design and implement a training plan that comports well with its particular characteristics. Training sessions for new employees should begin as soon as possible after their start date.

Finally, the agency suggests that practices will want to hold full-staff training sessions each year, addressing billing and coding, and practice standards. Practices that have heretofore never conducted a compliance meeting may want to consider engaging a professional coding instructor, consultant or managed care representative to moderate. Whatever form this seminar takes, however, the following three key points should be emphasized: (1) The practice is committed to providing necessary training and continuing education; (2) It is a mandatory part of employees' regular job duties to complete this training; and (3) Employees must comply fully with all state and federal regulations as well as written practice policies as a condition of continued employment.

Step Five—Decide How to Respond to Detected Offenses

If your review leads to the discovery of violations, you will need to know how to respond, both in terms of reporting your problem and taking steps to rectify it. The OIG notes that the specific corrective action should depend on the circumstances, and, in some cases, may be a straightforward repayment with the appropriate explanation to the applicable payor from which the overpayment was received. Although restitution of overpayments is a viable option, given the severe civil and criminal penalties involved, practices would be wise to seek assistance from experienced health care counsel when confronted with these issues.

Step Six—Put Open Lines of Communication into Place

It is essential that practices impress upon their employees that they have nothing to fear from reporting instances of non-compliance. Given human nature's predilection for avoiding controversy, this is a disheartening challenge. Nevertheless, staffers must be made to understand that they put themselves and the entire practice at risk by failing to report. Employees should be encouraged to report their concerns directly to managers or physicians. Practices that put their policies in writing, post and circulate them, and train their employees well are already taking steps to comply with the agency's suggestion in this respect.

Step Seven—Enforce Your Disciplinary Standards Through Well-Publicized Guidelines

It must be made clear that non-compliance, even those instances which occur as a result of error, endangers the entire operation and simply cannot be tolerated. The OIG suggests that penalties be set forth clearly and enforced without exception. Practices may want to consider employing a hierarchy of sanctions, designed to correspond to repeated instances of non-compliance. Practices should be prepared to demote, reassign or fire a continually non-compliant employee. If it is necessary to discharge someone, practices should document fully the reasons therefor, as well as inform other staffers that the employee was let go for his or her failure to adhere to practice policy.

Conclusion

As with the draft Guidance, the final Guidance encourages physician practices to participate in other entities' compliance programs, such as those of hospitals or physician practice management companies, in order to promote the desired compliance objective without imposing excessive burdens on the practice. However, the final Guidance also warns physicians of the potential anti-kickback and self-referral issues that may arise as a result of such collaborative efforts, recommending "physicians consider limiting their participation in a sponsoring provider's compliance program to areas of training and education or policies and procedures."

Given the microscopic level of review to which health care entities and endeavors are so frequently subjected in today's enforcement environment, as well as the OIG's sustained interest in compliance, physician practices should seriously consider undertaking compliance activities. While the final Guidance is voluntary, physician practices, with assistance from legal counsel, can use the OIG's document as a valuable tool in

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developing and implementing practical and cost-effective compliance measures in their practices, thereby enhancing their own security.

The OIG's guidance is available on the World Wide Web at: <http://www.hhs.gov/oig/modcomp/cpc.pdf>

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